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10/534,160	05/05/2005	Francois Jean-Charles Natt	DC/4-32768A	9963
75/074 75/90 08/20/2008 NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 400 TECHNOLOGY SQUARE CAMBRIDGE, MA 02139				
EXAMINER				
MCINTOSH III, TRAVIS C				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## RESPONSE TO AMENDMENT AFTER FINAL

Regarding applicant's arguments that the 1/11/2008 office action should not have been final. Applicants argue that the sole grounds of rejection in the Final rejection was an obviousness rejection that had not been previously raised; and/or the submission of the 10/10/2007 IDS was not enough to render the next office action final.

The examiner respectfully disagrees. Because the rejection was not necessitated by amendments to the claims does not mean the next rejection can not be made final. The MPEP 609.04(b) states:

### 2. Final Rejection Is Appropriate

The information submitted with a statement under 37 CFR 1.97(e) can be used in a new ground of rejection and the next Office action can be made final, if the new ground of rejection was necessitated by amendment of the application by applicant. **Where the information is submitted during this period with a fee as set forth in 37 CFR 1.17(p), the examiner may use the information submitted, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner.** See MPEP § 706.07(a).

This is the exact situation in the instant application. Applicants filed an IDS after the 1<sup>st</sup> action on merits and paid the fee as set forth in 1.17(p), thus rendering the previous finality proper. Applicant's arguments drawn to "a final rejection is improper where the new ground of rejection introduced by the Examiner after an IDS submission was not necessitated by amendment to the claims" is improper regarding the situation currently set forth. Possibly such as when the IDS was filed with a statement under 37 CFR 1.97(e) or when the IDS is filed in response to a requirement under 37 CFR 1.105, neither of which was the situation here.

Regarding the 103 rejection.

Applicants argue that since Pitsch does not provide a basis to reject Si-linked hetero atoms, then it cannot render obvious compounds having Si linked to tertiary carbon atoms. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Pitsch is cited to teach triisopropylsilyl protecting groups. Gunderson is cited to teach compounds and methods of protecting hydroxy groups with tert-butyldimethylsilyloxy groups, thus the combinations of the 2 references renders obvious the siloxymethyl derivatives having a tertiary carbon atom.

Applicants arguing that because the Pitsch references relate to similar subject matter a strong presumption is raised that the authors were completely unaware of the tertiary carbon atom substituents. However, this is not seen to be patentably relevant or convincing. This is why a 103 rejection was made, if all the elements claimed herein were found in the Pitsch reference a 102 rejection based on anticipation would have been made. The examiner believes that if a skilled artisan looked at Pitsch and Gunderson together, the instantly rejected claims would have been obvious.

Applicants also argue that the protecting groups of Gunderson are for reactions with sterically hindered alcohols, however, this does not mean they would also not be appropriate for compounds which are not sterically hindered. Because Pitsch failed to recognize that certain compounds of the Gunderson reference could be applied to his discovery does not mean the 2 references are not properly combinable under 35 USC 103(a).

Moreover, applicants statement on page 7 of their response wherein applicants state that "Applicant noted that Examiner apparently acknowledges that there is no teaching/suggestion/motivation (T/S/M) to combine the references he cites" is unfounded and incorrect. Nowhere did the examiner acknowledge or state that there is no teaching/suggestion/motivation in the references, but the examiner was rather stating what was taught by the recent KSR decision. Applicant's interpretation of the examiner's statements were incorrect. For clarity, the following is from MPEP 2143:

\*\*>The Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

#### EXEMPLARY RATIONALES

Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.

The rationale used for the instant case could fall under any or all of (A), (B), (E), or (G), at the minimum. Claimed protecting groups are known in the art. The claim's core is known in the art. Modifying one protecting group for another is seen to be obvious to one of skill in the art. One may not necessarily find it obvious to protect a hydroxy group the same as they would an amino group in various reactions, but it would be at least obvious to try to protect a hydroxy group with many of various known hydroxy protecting groups in a variety of reactions. This is further evidenced by applicant's claims 15 and 17 for example, which state that  $R_2$  and  $R_3$  are "a protecting group". If there was such criticality and specificity to the requirement for which protecting groups are required for synthetic protocols and which are not, the examiner believes applicant's would have required these groups to be specific protecting groups, rather than any protecting group which is available for hydroxy groups.

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623